UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): December 10, 2021

Allogene Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-38693	82-3562771
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

210 East Grand Avenue, South San Francisco, California 94080
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 457-2700
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALLO**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§ 240.12b–2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On December 10, 2021 Allogene Therapeutics, Inc. (the "Company") amended its Lease Agreement (as amended, the "HQ Lease") with Britannia Pointe Grand Limited Partnership to lease an additional 47,566 square feet of office and laboratory space in South San Francisco, California, as part of the same building as the Company's current headquarters, which consist of approximately 68,072 square feet of office and laboratory space. The HQ Lease relating to the expansion premises is expected to commence on April 1, 2022. Subject to commencement and rent abatement for the first four months, the Company will be required to pay $309,179, or $6.50 per square foot, for the expansion space. Thereafter the price per square foot will increase at a rate of approximately 3.5% per year. The HQ Lease for both the existing and expansion premises will expire on March 31, 2032. Upon certain conditions, the Company has an option to extend the Lease for an additional eight years. In connection with the HQ Lease, the Company will increase its letter of credit for the benefit of the landlord to $1,779,784.

In addition, on December 10, 2021, the Company amended its Lease Agreement with Healthpeak Properties, Inc. (as amended, the "Lease"), of approximately 14,943 square feet of office and laboratory space in South San Francisco, California, near the Company's headquarters, to extend the term of the Lease to be co-terminus with the HQ Lease.

The foregoing description of the amendments to the HQ Lease and Lease does not purport to be complete and is qualified in its entirety by reference to the full and complete terms of the amendments, a copy of which will be filed as an exhibit to a subsequent filing with the Securities and Exchange Commission.

Item 8.01 Other Events.

On December 13, 2021, the Company, in collaboration with Les Laboratoires Servier SAS and Institut de Recherches Internationales Servier SAS, an independent international pharmaceutical company (together, "Servier"), announced results from the Phase 1 ALPHA trial of ALLO-501 and from the Phase 1 ALPHA2 trial of ALLO-501A in relapsed/refractory ("r/r") non-Hodgkin lymphoma at the 63rd American Society of Hematology ("ASH") Annual Meeting. In addition, the Company announced results from the Phase 1 UNIVERSAL study of single dose ALLO-715 in r/r multiple myeloma at the ASH Annual Meeting.

Results from the Phase 1 ALLO-501 ALPHA Trial and the Phase 1 ALLO-501A ALPHA2 Trial

The ALPHA and ALPHA2 trial enrollment information is set forth in the table below.

	ALPHA	ALPHA2
Data Cutoff	October 18, 2021	
Enrolled	50	29
Evaluable for Safety	49*	28**
Evaluable for Efficacy	40[#]	25[†]
% Initiated Treatment	98%	97%
Median Days Enrollment to Treatment Initiation	5	2

[*] One patient unable to be treated due to rapidly progressing disease
[**] One patient developed COVID-19 before treatment
[#] Only CAR T Naïve subjects presented from ALPHA at ASH 2021
[†]One patient started LD but became ineligible due to central nervous system disease progression; two treated patients yet to reach tumor assessment at data cutoff

Patients received lymphodepletion ("LD") containing fludarabine (30mg/m^2 x 3 days), cyclophosphamide ("Cy") (300mg/m^2 x 3 days) and ALLO-647 (30, 60 or 90mg) followed by escalating dose levels ("DL") of ALLO-501 or ALLO-501A. In consolidation, patients with stable disease or better at day 28 received a chemotherapy-free lymphodepletion (ALLO-647 only) and AlloCAR T™ cell infusion (120 x 10^6 CAR+ T cells). The trials explored two consolidation cohorts. Consolidation 1 used the standard Cy dosing (300mg/m^2 x 3 days). Consolidation 2 explored a higher Cy dose (500mg/m^2 x 3 days).

Response Rates Across the ALPHA and ALPHA2 Trials

ALPHA ALLO-501 Response Rates

	Follicular Lymphoma ("FL")			Large B Cell Lymphoma ("LBCL")			
	Single dose (N=18)	Cons (N=8)	All FL (N=26)	Single dose (N=11)	Cons (N=3)	All LBCL (N=14)	All Patients (N=40)

Overall Response Rate (“ORR”), n (%)	14 (78%)	7 (88%)	21 (81%)	7 (64%)	2 (67%)	9 (64%)	30 (75%)
CR, n (%)	9 (50%)	6 (75%)	15 (58%)	5 (45%)	1 (33%)	6 (43%)	21 (53%)

Consolidation 1 and 2 combined due to limited sample size at the time of the data cutoff

Among the 21 FL patients and 11 LBCL patients who were autologous CAR T naïve, 33% and 36% achieved a complete response (“CR”) at six months. With the exception of one previously disclosed patient who died from unrelated arrhythmia, all LBCL patients who achieved a CR at month six remain in CR with the longest ongoing CR at 18+ months.

ALPHA2 ALLO-501A Response Rates

	DL1/DL2 (N=6)	Cons 1 (N=9)	Cons 2 (N=10)	All Patients (N=25)
ORR, n (%)	2 (33%)	4 (44%)	6 (60%)	12 (48%)
CR, n (%)	2 (33%)	4 (44%)	1 (10%)	7 (28%)
Longest CR (months)	15+	9+	4+	15+

All patients who achieved a CR at month six remain in CR with the longest ongoing CR at 15+ months and longest ongoing CRs in the consolidation cohort at 9+ months.

Combined ALPHA + ALPHA2 Consolidation Response Rates

	Consolidation 1	Consolidation 2	All Patients
	N = 16	N = 14	N = 30
ORR, n (%)	**9 (56%)**	10 (71%)	19 (63%)
CR, n (%)	**7 (44%)**	5 (36%)	12 (40%)

Consolidation dosing was associated with meaningful cell expansion after the second dose of AlloCAR T cells. As noted in the ALPHA response rate table, consolidation was associated with a higher ORR (88% vs. 78%) and CR rate (75% vs. 50%) in FL patients versus a single dose of ALLO-501. All seven FL patients who responded to consolidation remain in response with the longest ongoing response at seven months. In the combined Consolidation 1 cohort, four partial responses (“PR”) converted to CR following the second administration of cells with six of the seven patients in this regimen who achieved CRs remaining in CR.

Safety Across the ALPHA and ALPHA2 Trials

AlloCAR T therapy was associated with consistent and manageable safety with no dose limiting toxicities (“DLTs”) or graft-vs-host disease (“GvHD”), and minimal Grade 3 Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), or Grade 3 cytokine release syndrome (“CRS”). Consolidation 1 presented a superior safety profile across all cohorts.

ALPHA ALLO-501 Safety

	DL1 40M (N=4)		DL2 120M (N=16)		DL3 360M (N=18)		Cons (N=11)		All Patients (N=49)	
	All	Gr3+	All	Gr3+	All	Gr3+	All	Gr3+	All	Gr3+
IRR*	50%	0	69%	6%	61%	0	64%	18%	63%	6%
CRS	0	0	31%	6%	33%	0	27%	9%	29%	4%
Neurotoxicity	25%	0	25%	6%	22%	0	36%	9%	27%	4%
GvHD	0	0	0	0	0	0	0	0	0	0
Infection	75%	0	63%	38%	61%	17%	64%	36%	63%	27%
Neutropenia	100%	75%	75%	75%	83%	72%	82%	64%	82%	71%
Serious Adverse Event ("AE")	25%		56%		28%		27%		37%	

*Infusion-related reactions ("IRR").

Grade 3+ infection rates were observed at a rate similar to that seen in autologous CAR T trials. There were five treatment-emergent deaths in the absence of disease progression, all of which were previously reported.

ALPHA2 ALLO-501A Safety

	DL1 40M (N=1)		DL2 120M (N=6)		**Cons 1 (N=11)**		Cons 2 (N=10)		All Patients (N=28)	
	All Gr	Gr 3+	All Gr	Gr 3+	**All Gr**	**Gr 3+**	All Gr	Gr 3+	All Gr	Gr 3+
IRR	100%	0	33%	0	**27%**	**0**	10%	0	25%	0
CRS	100%	0	17%	0	**0**	**0**	10%	0	11%	0
Neurotoxicity	100%	0	33%	0	**9%**	**0**	20%	0	21%	0
GvHD	0	0	0	0	**0**	**0**	0	0	0	0
Infection	100%	0	83%	17%	**27%**	**0**	10%	10%	36%	7%
Neutropenia	0	0	100%	100%	**36%**	**36%**	60%	60%	57%	57%
Serious AE	0		100%		**18%**		30%		39%	

The safety profile of ALLO-501A was manageable in both the single-dose and both consolidation cohorts. There were no treatment-emergent deaths in the trial. Adverse events of interest in the single-dose cohort were previously reported at the 2021 American Society of Clinical Oncology Annual Meeting. A chromosomal abnormality is being investigated in a patient in Consolidation 2, which has resulted in a clinical hold on the ALPHA and ALPHA2 trials.

Pending resolution of the clinical hold and ongoing discussion with the U.S. Food and Drug Administration (FDA), the Company intends to initiate a Phase 2 pivotal trial in r/r LBCL utilizing the Consolidation 1 dosing regimen in 2022. In the ALPHA and ALPHA2 trials, this regimen was easy to administer and associated with a favorable safety profile, CR rates on par with autologous CAR T therapies, and supportive biomarker data.

Results from the Phase 1 ALLO-715 UNIVERSAL Trial

As of the October 14, 2021 data cutoff, 48 patients were enrolled with 43 patients evaluable for safety and efficacy. Patients were refractory to their last line of myeloma therapy, had a median of five prior lines of therapy, and 42% were penta-refractory meaning the disease has ultimately become nonresponsive to other approved therapies. Five patients became ineligible for treatment due to rapidly progressing disease. The median time from enrollment to the start of therapy was five days.

The Phase 1 UNIVERSAL trial evaluated lymphodepletion followed by ALLO-715 at one of four dose levels (DL1=40M cells, DL2=160M cells, DL3=320M cells, DL4 = 480M cells) and two LD regimens (FCA: fludarabine, Cy and ALLO-647 or CA: Cy and ALLO-647 only). The updated presentation primarily focuses on the optimized DL3 cell dose and FCA lymphodepletion.

The higher CAR T cell doses were associated with an increased response rate and greater AlloCAR T^{tm} cell expansion. In the DL3 cohort which was selected for cohort expansion, the ORR increased from 60% reported at ASH 2020 to 71% with 46% of patients achieving a very good partial response ("VGPR") or better ("VGPR+") up from 40%. VGPR+ is defined as a stringent complete response ("sCR"), CR or VGPR. Of the patients who achieved VGPR+, 92% were Minimal Residual Disease negative.

	FCA			
Cell dose and LD regimen	DL3 320 x 10^6 CAR+ cells			
	Low ALLO-647 (N=11)	Mid ALLO-647 (N=10)	High ALLO-647 (N=3)	**ALL ALLO-647 (N=24)**
ORR, n (%)	7 (64%)	8 (80%)	2 (67%)	**17 (71%)**
VGPR+ Rate, n (%)	5 (46%)	5 (50%)	1 (33%)	**11 (46%)**
CR/sCR Rate, n (%)	3 (27%)	3 (30%)	0	**6 (25%)**

As of the data cutoff, the overall median follow-up for efficacy was 3.8 months. The median duration of response is 8.3 months, with nine patients remaining in ongoing response at the time of the data cut-off. The longest ongoing response after cell infusion is 12 months. Results showed that soluble BCMA levels were 10 times lower in responders at day 28, suggesting soluble BCMA suppression is associated with response.

Of the 43 patients evaluable for safety, there was no GvHD. Grade 1 and 2 CRS was reported in 23 patients (53%) and was manageable with standard therapies. In this heavily pre-treated patient population, infection occurred in 54% of patients, which included three Grade 5 infections, two of which were previously reported. Grade 3+ neutropenia occurred in 70% of patients.

Six patients (14%) experienced adverse events of low-grade neurotoxicity, which was reversible. Use of tocilizumab and steroids was infrequent (23% and 14%, respectively).

Adverse Events of Interest	Grade 1 N (%)	Grade 2 N (%)	Grade 3 N (%)	Grade 4 N (%)	Grade 5 N (%)	All Grades N (%)
CRS	13 (30%)	10 (23%)	1 (2%)	0	0	24 (56%)
Neurotoxicity	4 (9%)	2 (5%)	0	0	0	6 (14%)
GvHD	0	0	0	0	0	0
Infection	3 (7%)	10 (23%)	7 (16%)	0	3 (7%)	23 (54%)
Infusion Reaction to ALLO-647	7 (16%)	5 (12%)	0	0	0	12 (28%)

Subject to the clinical hold currently in place, the Company continues to target 2022 for data from additional strategies, including from consolidated dosing of ALLO-715 using ALLO-647, ALLO-715 in combination with SpringWorks Therapeutics' investigational gamma secretase inhibitor, nirogacestat, and the Phase 1 dose escalation portion of the IGNITE trial evaluating ALLO-605, the Company's first TurboCAR™ candidate, targeting BCMA for r/r multiple myeloma.

Cautionary Note on Forward-Looking Statements and Other Information

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The press release may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the timing and ability to progress the ALPHA2 trial and proceed to the Phase 2 portion of the trial; the timing and ability to progress the UNIVERSAL trial and IGNITE trial and present any data from the trials; clinical outcomes, which may materially change as more patient data become available; the ability to resolve the current clinical hold on the Company's trials; and the potential benefits of AlloCAR T™ therapy. Various factors may cause differences between Allogene's expectations and actual results as discussed in greater detail in Allogene's filings with the SEC, including without limitation in its Form 10-Q for the quarter ended September 30, 2021. Any forward-looking statements that are made in this Form 8-K speak only as of the date hereof. The Company assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date hereof.

Statements regarding anti-CD19 autologous CAR T data are based on review of Kymriah United States product insert (USPI), Schuster S et al NEJM 2019; Yescarta USPI, Locke, AACR 2017; and Breyanzi USPI. Statements regarding anti-BCMA autologous CAR T data are based on review of Berdeja, Lancet, 2021 and Munshi, NEJM, 2021. Caution should be exercised when interpreting results from separate trials involving separate product candidates. There are differences in the clinical trial design, patient populations, published data, follow-up times and the product candidates themselves, and the results from the clinical trials of autologous products may have no interpretative value on our existing or future results.

The Company's AlloCAR T™ programs utilize Cellectis technologies. ALLO-501 and ALLO-501A are anti-CD19 products being jointly developed under a collaboration agreement between Servier and the Company based on an exclusive license granted by Cellectis to Servier. Servier grants to the Company exclusive rights to ALLO-501 and ALLO-501A in the U.S. while Servier retains exclusive rights for all other countries. ALLO-715 and ALLO-605 target BCMA. The Company has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA and holds all global development and commercial rights for these investigational candidates.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALLOGENE THERAPEUTICS, INC.

By: /s/ David Chang, M.D., Ph.D.
David Chang, M.D., Ph.D.
President, Chief Executive Officer

Dated: December 15, 2021